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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/777,554	02/06/2001	Barbara Scott	BBC-077/A.	8200

7590 06/22/2004

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EXAMINER

SHIAO, REI TSANG

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 06/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/777,554

Applicant(s)

SCOTT ET AL.

Examiner

Robert Shiao

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on responses filed on 5/03, 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) 23-37, 59 and 60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 and 38-58 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 0604.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

1. This application claims benefit of the provisional application: 60/180,841 with a filing date 02/07, 2000.
2. Amendment of claims 58-60 in Paper No. 0204, dated February 9, 2004, is acknowledged. Claims 1-60 are pending in the application.

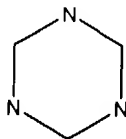
### Response to Election/Restriction

3. Applicant's election with traverse of Group I claims 1-22, and 38-58, in part, in Paper No. 0504, dated May 03, 2004, is acknowledged. The traversal is on the grounds that (1) Groups I-VII share a structural commonality of the benzothiazole; and (2) no a substantially greater burden for searching Groups I-VII, and M.P.E.P 802.01 is cited. This is not found persuasive and reasons are given, *infra*.

### Status of the Claims

4. Claims 1-60 are pending in the application. The scope of the invention of the elected subject matter is as follows:

Claims 1-22, and 38-58, in part, drawn to compounds/compositions of formula (I), wherein the variable Q represents hydrogen thereof; the variables Q and X<sup>1</sup>, and two

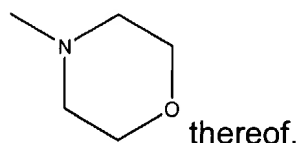
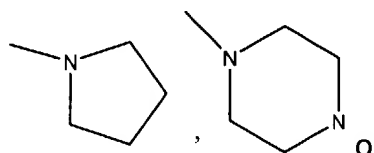


nitrogen atoms, are not together to form the ring; the variable Y represents O or S; the variable W does not represent heteroaryl or heterocycle (i.e., morpholine, piperidine, etc) moiety, and the variable W is not substituted with heteroaryl or

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heterocycle (i.e., morpholine, piperidine, etc) moiety thereof; the variable  $X^1$  does not represent heteroaryl or heterocycle (i.e., morpholine, piperidine, etc) moiety, and the variable  $X^1$  is not substituted with heteroaryl or heterocycle (i.e., morpholine, piperidine, etc) moiety thereof, the variables  $R^1$ ,  $R^2$ , and  $R^3$  independently do not represent heteroaryl or heterocycle (i.e., morpholine, piperidine, etc) moiety, the variables  $R^1$ ,  $R^2$ , and  $R^3$  independently are not substituted with heteroaryl or heterocycle (i.e., morpholine, piperidine, etc) moiety; the variables  $R^1$  and W together with their attached carbons do not form a 5- or 6-membered heterocyclcyl ring thereof;  $R^3$  and  $X^1$  together

with the nitrogen atom do not form a heterocycle ring



thereof.

The above mentioned withdrawn compounds which are withdrawn from consideration as being for non-elected subject matter differ materially in structure and composition from the compounds of the elected invention. The withdrawn compounds contain varying functional groups (i.e., heterocycle) which differ from those of the elected invention such as piperazine, morpholine, pyridazine, pyrimidine, thiazole, oxazole, etc, which are chemically recognized to differ in structure and function. This recognized chemical diversity of the functional groups can be seen by the various classification of these functional groups in the U.S. classification system, i.e., class 544 subclass 358(+) (piperazine), class 544 subclass 106(+) (morpholine), class 544

subclass 224 (+) (pyridazine), class 544 subclass 242 (+) (pyrimidine), class 548 subclass 146(+) (thiazole), class 548 subclass 215(+) (oxazole), etc. Therefore, again, the compounds which are withdrawn from consideration as being for non-elected subject matter differ materially in structure and composition and have been restricted properly.

The Markush group set forth in the claims includes both independent and distinct inventions, and patentably distinct compounds (or species) within each invention. However, this application discloses and claims a plurality of patentably distinct inventions far too numerous to list individually. Moreover, each of these inventions contains a plurality of patentably distinct compounds, also far too numerous to list individually. For these reasons provided below, restriction to one of the following Groups is required under 35 U.S.C. 121, wherein an Group is a set of patentably distinct inventions of a broad statutory category (e.g. Compounds, Methods of Use, Methods of Making, etc.).

The inventions are independent and distinct because there is no patentable co-action between the groups and a reference anticipating one member will not render another obvious. Each group is directed to art recognized divergent subject matter which require different searching strategies for each group. Moreover, the examiner must perform a commercial database search on the subject matter of each group in addition to a paper search, which is quite burdensome to the examiner.

The invention claims 1-22, and 38-58, in part, embraced in above elected subject matter are prosecuted in the case. Claims 1-22, and 38-58, in part, not embraced in

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above elected subject matter, and claims 23-37, and 59-60 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

The requirement is still deemed proper and is therefore made **FINAL**.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1-22, and 38-58 are rejected under 35 U.S.C. 102(a,b) as being anticipated by (1) Duncia et al. US 6,214,851, see CAS: 133:252423; (2) Sawhney et al. publication, Indian Journal of Chemistry, Section B: Organic Chemistry Including Medicinal Chemistry (1983), 22B(10), 1044-9, see CAS:100:139014; (3) Bhattacharya et al. publication, Wear (1990), 136(2), 345-57, see CAS:113:100536.

Applicants claim benzothiazole compounds of formula (I) as protein kinase inhibitors, and the compounds are found in the page 11-51 of the instant specification.

Duncia et al. disclose a compound Urea, N-(4-chloro-2-benzothiazolyl)-N'-tricyclo[3.3.1.1<sup>3,7</sup>]dec-1-yl-, clearly anticipate the instant compound of formula (I), wherein the variable R<sup>1</sup> represents hydrogen; the variable R<sup>2</sup> represents halogen (i.e., Cl); the variables W and Q independently represents hydrogen; the variable Y represents O; the variable X<sup>1</sup> represents hydrogen; the variable R<sup>3</sup> represents

cycloalkyl, see RN:295787-87-0 of CAS:133:252423.

Sawhney et al. disclose a compound Thiourea, (6-methyl-2-benzothiazolyl)-, clearly anticipate the instant compound of formula (I), wherein the variable  $R^1$  and  $R^2$  independently represents hydrogen; the variables W represents alkyl; and the variable Q represents hydrogen; the variable Y represents S; the variable  $X^1$  represents hydrogen; the variable  $R^3$  represents hydrogen, see RN:52112-82-0 of CAS:100:139014.

Bhattacharya et al. a compound Benzamide, N-[[[6-methyl-2-benzothiazolyl) amino]thioxomethyl]-, clearly anticipate the instant compound of formula (I), wherein the variable  $R^1$  and  $R^2$  independently represents hydrogen; the variables W represents alkyl; and the variable Q represents hydrogen; the variable Y represents S; the variable  $X^1$  represents hydrogen; the variable  $R^3$  represents acyl, see RN: 52112-81-9 of CAS:113:100536.

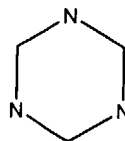
### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

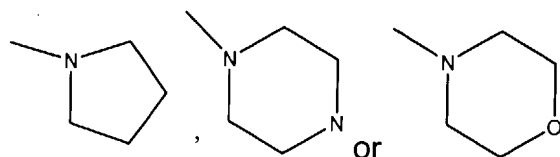
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1-22, and 38-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Das et al. US 2002/0123484 A1. Das et al. '484 is 102(e) references.

Applicants claim benzothiazole compounds of formula (I) as protein kinase inhibitors, wherein the variable Q represents hydrogen thereof; the variables Q and X<sup>1</sup>,



and two nitrogen atoms, are not together to form the ring; the variable Y represents O or S; the variable W does not represent heteroaryl or heterocycle (i.e., morpholine, piperidine, etc) moiety, and the variable W is not substituted with heteroaryl or heterocycle (i.e., morpholine, piperidine, etc) moiety thereof; the variable X<sup>1</sup> does not represent heteroaryl or heterocycle (i.e., morpholine, piperidine, etc) moiety, and the variable X<sup>1</sup> is not substituted with heteroaryl or heterocycle (i.e., morpholine, piperidine, etc) moiety thereof, the variables R<sup>1</sup>, R<sup>2</sup>, and R<sup>3</sup> independently do not represent heteroaryl or heterocycle (i.e., morpholine, piperidine, etc) moiety, the variables R<sup>1</sup>, R<sup>2</sup>, and R<sup>3</sup> independently are not substituted with heteroaryl or heterocycle (i.e., morpholine, piperidine, etc) moiety; the variables R<sup>1</sup> and W together with their attached carbons do not form a 5- or 6-membered heterocyclyl ring thereof; R<sup>3</sup> and X<sup>1</sup> together with the nitrogen atom do not form a heterocycle ring

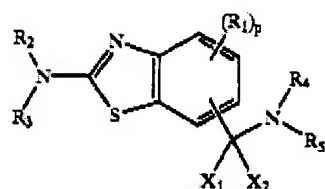


thereof. The compounds are found in the page 11-51 of the instant specification.

**Determination of the scope and content of the prior art (MPEP §2141.01)**

Das et al. disclose a compound of formula (I) as protein kinase inhibitors,





, wherein the variable R<sub>1</sub>, R<sub>2</sub>, R<sub>4</sub>, and R<sub>5</sub> independently represents hydrogen, halo, cyano, nitro, alkyl, -C(O)qR<sub>6</sub>, and R<sub>6</sub> represents alkyl; and the variable p is 0 or 1; the variable X<sub>1</sub> and X<sub>2</sub> independently represent hydrogen; the variable R<sub>3</sub> represents -Z<sub>13</sub>-NR<sub>7</sub>R<sub>8</sub>, and Z<sub>13</sub> represents -Z<sub>11</sub>-C(S)-Z<sub>12</sub>, Z<sub>11</sub> and Z<sub>12</sub> independently represent a bond, R<sub>7</sub> and R<sub>8</sub> independently represent hydrogen, alkyl, alkenyl, alkynyl, cycloalkyl, or -C(O)qR<sub>6</sub>, and R<sub>6</sub> represents alkyl, the variable q is 1 or 2; see columns 18-19. A number of examples have been specifically exemplified, see columns 14-17.

**Determination of the difference between the prior art and the claims (MPEP**

**§2141.02)**

The difference between instant claims and Das et al. is that the instant variable Y represents O or S, while Das et al. represent S at the same position.

**Finding of prima facie obviousness-rational and motivation (MPEP §2142-2143)**

One having ordinary skill in the art would find the claims prima facie obvious **because** one would be motivated to employ the compounds of Das et al. to obtain a compound of formula (I), wherein the variable Q represents hydrogen thereof; the variable Y represents S; the variable W represent H, Cl, NO<sub>2</sub>, substituted alkyl, etc; the variable X<sup>1</sup> represent hydrogen or alkyl; the variables R<sup>1</sup>, R<sup>2</sup>, and R<sup>3</sup> independently

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represent hydrogen, alkyl, nitro, amino,  $\text{NHX}_3$ , or  $\text{NX}_3\text{X}_3$ , and  $\text{X}_3$  is hydrogen, alkyl, or aryl.

The motivation to make the claimed compounds derives from the expectation that the instant claimed compounds derived from known Das et al. compounds would possess similar activity (i.e., protein kinase inhibitors) to that which is claimed in the reference.

### ***Objection***

7. Claims 1-22, and 38-58 are objected to as containing non-elected subject matter heterocycle, i.e., pyridyl of claim 2. It is suggested that applicants amend the claims to the scope of the elected subject matter as defined on pages 2-3 *supra*.

### ***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Shiao whose telephone number is (571) 272-0707. The examiner can normally be reached on 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

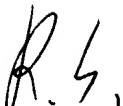
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for


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published applications may be obtained from either Private PAIR or Public PAIR.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Robert Shiao, Ph.D.  
Patent Examiner  
Art Unit 1626

  
*for* Joseph K. McKane  
Supervisory Patent Examiner  
Art Unit 1626

June 17, 2004